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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,796	07/24/2002	William J. Bologna	117-389	1022

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EXAMINER
GEORGE, KONATA M

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,796	BOLOGNA ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,13-22,36 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13-22,36 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,8,10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-10, 13-22, 36 and 37 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on April 4, 2002; August 15, 2002; and December 20, 2002 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Specification

2. Specification contains reference to US Patent Application Serial Number 09/145,172, which has now become a Patent No. 6,126,959. Please correct the specification to reflect the application becoming a patent.

3. The use of the trademark Replens®, Crinone® and advantage-S® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

4. On page 12, line 24 there is a typographical error. It reads " -adrenergic agonist". Correction is needed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-10, 36 and 37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 13-15 of U.S. Patent No. 6,126,959. Although the conflicting claims are not identical, they are not patentably distinct from each other because the intended use limitations of the instant compositions do not patentably distinguish over '959 and the instant method claims would be inherent of the method claims in '959.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1-3 and 6-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Harrison et al (US Pat. No. 6,197,327).

Harrison discloses a device and method for treatment of dysmenorrhea (i.e. primary or secondary). Column 2, line 20, describe the use of β-adrenergic agonists such as terbutaline in the treatment of dysmenorrhea. One embodiment of the invention further comprises a biocompatible excipient (col. 2, lines 32-36). Examples of excipients include glycerin, mineral oil, polycarbophil, etc. (col. 2, lines 60-63). Column 2, lines 25-31, teach the different types of drug delivery forms such as tablets, bioadhesive tablets, etc. Example 9, column 15, lines 45-67, describe preparations of compositions comprising different drugs one of which is terbutaline (5mg). The drugs of the composition in example 9 can be substituted for the drugs in examples 4-7. Example 7, lines 5-10, teach the use of ibuprofen added to a gel comprising one of several different ingredients one of which is polycarbophil. Therefore, it is the position of the examiner that the use of terbutaline in the composition of example 7 containing polycarbophil is read on the claimed invention. Intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

7. Claims 13-19 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Harrison et al (US Pat. No. 6,197,327) as evidenced by Peterson et al. (US Pat. No. 6,207,696 B1).

Harrison discloses a device and method for treatment of dysmenorrhea (i.e. primary or secondary). Column 2, line 20, describe the use of β-adrenergic agonists such as terbutaline in the treatment of dysmenorrhea. One embodiment of the invention further comprises a biocompatible excipient (col. 2, lines 32-36). Examples of excipients include glycerin, mineral oil, polycarbophil, etc. (col. 2, lines 60-63). Column 2, lines 25-31, teach the different types of drug delivery forms such as tablets, bioadhesive tablets, etc. Example 9, column 15, lines 45-67, describe preparations of compositions comprising different drugs one of which is terbutaline (5mg). The drugs of the composition in example 9 can be substituted for the drugs in examples 4-7. Example 7, lines 5-10, teach the use of ibuprofen added to a gel comprising one of several different ingredients one of which is polycarbophil. Therefore, it is the position of the examiner that the use of terbutaline in the composition of example 7 containing polycarbophil is read on the claimed invention. Peterson is relied upon to teach for the showing that secondary dysmenorrhea is the pain associated with endometriosis (col. 4, lines 32-33) (see MPEP 2131.01 for multiple reference 35 U.S.C. 102 rejections). Therefore, a woman having dysmenorrhea resulting from endometriosis would be given the composition of Harrison. The claiming of new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable, *In re Best,* 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

8. Claims 6 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Peterson et al. (US Pat. No. 6,207,696 B1).

Peterson teaches compositions and methods for the treatment of dysmenorrhea, endometriosis. Peterson teaches histidine as a therapeutically active agent (col.4, lines 26-44). However, column 8, line 48 through column 9, line 5, teaches that another therapeutically active agent which are useful for treating endometrial pain such as β-adrenergic agonists i.e. terbutalin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 4, 5, 20, 21, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrison et al (US Pat. No. 6,197,327) in view of Peterson et al. (US Pat. No. 6,207,696 B1).

Harrison discloses a device and method for treatment of dysmenorrhea (i.e. primary or secondary). Column 2, line 20, describe the use of β-adrenergic agonists such as terbutaline in the treatment of dysmenorrhea. One embodiment of the invention further comprises a biocompatible excipient (col. 2, lines 32-36). Examples of excipients include glycerin, mineral oil, polycarbophil, etc. (col. 2, lines 60-63). Column 2, lines 25-31, teach the different types of drug delivery forms such as tablets, bioadhesive tablets, etc. Example 9, column 15, lines 45-67, describe preparations of compositions comprising different drugs one of which is terbutaline (5mg). The drugs of

the composition in example 9 can be substituted for the drugs in examples 4-7. Example 7, lines 5-10, teach the use of ibuprofen added to a gel comprising one of several different ingredients one of which is polycarbophil. It is the position of the examiner that the use of terbutaline in the composition of example 7 containing polycarbophil is read on the claimed invention. Harrison does not teach the % weight of the active agent or the dosage regimen of the composition nor the treatment of endometriosis.

Peterson is relied upon to teach for the showing that secondary dysmenorrhea is the pain associated with endometriosis (col. 4, lines 32-33). Column 8, lines 48-52, teaches that when additional therapeutically active agents are added it is typically a pharmacologically recommended effective dose. Therefore, a woman having dysmenorrhea resulting from endometriosis would be given the composition of Harrison. The claiming of new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable, *In re Best,* 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

As for the limitation of % weight and dosage regimen it would be routinely determined by one of ordinary skill in the art, through minimal experimentation.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is

(703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached at (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George
Patent Examiner
Art Unit 1616